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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,361	09/11/2003	Manfred Bohn	02481.1580-02000	3001
38263	7590	03/15/2006	EXAMINER	
PROPAT, L.L.C. 425-C SOUTH SHARON AMITY ROAD CHARLOTTE, NC 28211-2841			YU, GINA C	
			ART UNIT	PAPER NUMBER

1617

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,361

Applicant(s)

BOHN ET AL

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 26-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 26-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of amendment filed on December 20, 2005.

Claims 1, 26-50 are pending. Claim rejections made under 35 U.S.C. §§ 102 and 103 as indicated in the previous Office action dated September 21, 2005 are maintained for the reasons of record. Obviousness double patenting rejection as indicated in the same Office action are also maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 26, 30, 33-35, 40-45, 48, and 49 are rejected under 35

U.S.C. 102(b) as being anticipated by Bernstein (US 4250164) as evidenced by Rossomando (US 4179304).

Bernstein teaches the application of glucocorticoids in commercial nail polish compositions for the treatment of psoriasis. Example 1 discloses a nail polish composition comprising Valisone lotion (betamethasone valerate in isopropyl alcohol and carboxy vinyl polymer) and Revlon clear nail polish.

While the reference does not explicitly disclose the constituents of the Revlon nail polish, it is viewed that the Revlon product used in the Bernstein example contains the nail polish ingredients of the present invention. See Rossomando, col. 1, line 67 – col. 2, line 6, which states, “a typical nail polish

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formulation as sold by Revlon, Inc., of New York has the following ingredients: butyl acetate, toluene, nitrocellulose, ethyl acetate, isopropyl alcohol, toluenesulfonamide/ formaldehyde resin, dibutyl phthalate, camphor . . . and malic acid.” See instant claims 33-35 and 40-45. The method of using the composition is taught in Examples 2-4. See instant claims 48 and 49.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 36-39, 46, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein as evidenced by Rossomando as applied to

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claims 1, 26, 30, 33-35, 40-45, 48, and 49 as above, and further in view of Bohn (US 5264206).

Bernstein fails to teach the film-formers of instant claims 36 and 37.

Bohn teaches nail lacquer compositions to treat mycoses of nails. The reference teaches that the film-forming agents of instant claim 36, which include polyvinyl acetate, copolymers of vinyl acetate, acrylic acid or crotonic acid or monoalkyl maleates, etc., are used to make nail lacquer compositions. See col. 2, line 58 – col. 4, line 28. See instant claims 36 and 38. The copolymer of methyl vinyl ether and mono-n-butyl maleate is especially preferred. See instant claim 37. The copolymer of instant claim 39 is taught in Example 2. The reference teaches that the film-formers can be mixed with cellulose nitrate (which is used in the Revlon nail polish composition). See col. 4, lines 18-23. The reference also teaches the solvents and additives commonly used in nail lacquer art, which include 2-hydroxy-4-methoxybenzophenone, ammonium sulfite, esters and salts of thioglycolic acid, urea, allantoin, enzymes, and salicylic acid. See col. 4, line 50 – col. 5, line 24. See instant claims 46 and 47.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Bernstein by substituting the nail lacquer composition with that of Bohn, as motivated by the latter reference, because both references are directed to nail lacquer compositions for treating antifungal infections. The skilled artisan would have had a reasonable expectation of successfully producing an anti-psoriasis nail lacquer composition with similar effects.

Claims 27-29, 31, 32, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernstein as evidenced by Rossomando as applied to claims 1, 26, 30, 33-35, 40-45, 48, and 49 as above, and further in view of Fredriksson (US 3966924).

Bernstein fails to teach the glucocorticoids of instant claim 27 and the amounts of the active ingredient as recited by applicants.

Fredriksson teaches composition and method for treating psoriasis by topically applying a composition comprising 0.01-5 % of a commercially available corticosteroid in a suitable vehicle. See abstract. The reference teaches using, among other corticosteroids, clobetasol propionate, desoximetasone, betamethasone dipropionate, prednisolone and derivatives, and halcinonide. See col. 1, line 57 – col. 2, line 16. See instant claims 27-29, 32, and 50. While the claim limitation of claim 31 requires at least 8 % by weight of glucocorticoid, examiner notes that differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It is viewed that one of ordinary skill in the art would have modified the amount of the glucocorticoid with the motivation to make an anti-psoriasis with increased antifungal strength. It is viewed obvious that the skilled artisan would

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have discovered the optimum or workable amount of the active ingredient by routine experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 26-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,352,686 B2.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to a nail polish composition comprising one or more glucocorticoids, one or more physiologically tolerable solvents, and one or more water-insoluble film-forming agents. The present method of using the composition is also claimed in the patent. The glucocorticoids, solvents, film-forming agents, and the additives that are recited in the instant claims are also claimed in the patent.

Response to Arguments

Applicant's arguments filed on December 20, 2005 have been fully considered but they are not persuasive.

Applicants assert that the anticipation rejection should be withdrawn because Rossomando refers to "a typical Revlon nail polish" and does not specifically teach "Revlon clear nail polish". Examiner respectfully disagrees, since Revlon clear nail polish belongs to a class of typical Revlon nail polish formulations. Furthermore, Bernstein teaches using any type of commercially available nail polish, and Revlon clear nail polish is only an example. Should applicants assert that Revlon clear nail polish does not contain the specifically recited components of the instant claims or those that are taught by Rossomando, applicants should submit factual evidence to support their position.

Applicants have submitted declaration filed on November 12, 2003 (originally signed with the parent application 09/135,657. Applicants also argue that, as indicated in the November 2003 declaration, that Revlon clear nail polish does not make a pharmaceutically active nail polish by mixing with Bernstein's lotion. The rejection here is made the claimed composition itself is anticipated by the teaching of the Bernstein reference. In order to overcome the rejection, applicants should show factual evidence as to the actual content of the Revlon clear nail polish formulation. Furthermore, examiner views that the experiment does not fairly illustrates the Bernstein teaching because the declaration does not indicate what amount of the Valisone lotion and the nail polish are combined, and the composition there are left without mixing and shaken after precipitation have

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formed. On the other hand, the prior art clearly teaches that the lotion and nail polish are mixed in 50:50 ratio.

With respect to the obviousness rejection in this case, examiner maintains the rejection and responses as made in the record.

Applicants assert that Bohn teaches away from combining film forming agents with large organic molecules as it emphasizes "the diffusional challenges associated with transdermal systems employing solidified drug reservoirs". Examiner views the argument unpersuasive because the quoted passage there refers to the problems of the previously known formulations that used nitrocellulose as film-former. The Bohn patent claims to have solved that problem by employing specific type of film-forming agents, which, in examiner's view, would have been the driving force of making the present invention.

Applicants also refer to Exhibit I in the declaration to argue that Bernstein's composition is unstable with the water insoluble film formers of Bohn. However, Exhibit I shows compositions comprising Valisone lotion and Revlon clear nail polish in an unidentified portions allowed sit without mixing. The data does not fairly show that teaching of the Bernstein/Bohn patent would have been nonobvious or produces greater than expected results. § MPEP 716.02.

Applicants also argue that the skin ointments of Fredricksson are "said to be disadvantageous [sic] in the present invention". It is respectfully pointed out that the ground of rejection here is not that such ointments are used to treat fingernails. It is the antifungal active agents, not the ointment vehicle, that the

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skilled artisan would have been motivated to combine with the Bernstein/Bohn nail polish.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 5:30 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



GREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER